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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,868	05/04/2001	Patrick L. Iversen	0450-0037.30	8375

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 09/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,868

Applicant(s)

IVERSEN ET AL.

Examiner

Karen Lacourciere

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12 and 23-38 drawn to an antisense molecule targeted to a splice acceptor site in human c-myc mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- II. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in myb mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- III. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in rel mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- IV. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in fos mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- V. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in jun mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- VI. Claims 1-7, 19, 20, 23-33, 37 and 38, drawn to an antisense molecule targeted to a splice acceptor site in human abl mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.

- VII. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in bcl mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- VIII. Claims 1-7, 17, 18, 23-33, 37 and 38, drawn to an antisense molecule targeted to a splice acceptor site in human p53 mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- IX. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in an integrin mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- X. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in a cathedrin mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- XI. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in a telomerase mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- XII. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in a cytokine mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- XIII. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in a kinase mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.

- XIV. Claims 1-7, 13, 14, 23-33, 37 and 38, drawn to an antisense molecule targeted to a splice acceptor site in human androgen receptor mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- XV. Claims 1-7, 15, 16, 23-33, 37 and 38, drawn to an antisense molecule targeted to a splice acceptor site in hCG β subunit mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- XVI. Claims 1-7, 21-33, 37 and 38, drawn to an antisense molecule targeted to a splice acceptor site in HIV rev mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- XVII. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in human papilloma virus mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.
- XVIII. Claims 1-7 and 23-33, drawn to an antisense molecule targeted to a splice acceptor site in human parvovirus B19mRNA and methods of inhibiting using the antisense, classified in class 536, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

Each of the inventions of Groups I-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different target molecules which are structurally distinct, wherein the antisense of each group is

Art Unit: 1635

structurally distinct based on the sequence of the target mRNA transcript. Further, the antisense and methods of using said antisense have different functions and different effects, in that each antisense functions to inhibit the expression of a biologically distinct target molecule and has the effect of down regulating a distinct activity.

Further, pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the antisense sequences listed in claims 9-22 and 35-38 are subject to a further restriction to one corresponding antisense sequence. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

Claims 9-22 and 35-38 specifically claim antisense SEQ ID NOS, which are targeted to and modulates the expression of myc (SEQ ID NO: 16-34), abl (SEQ ID NO: 37, 38), p53 (SEQ ID NO: 35, 36), androgen receptor (SEQ ID NO: 8, 9, 12, 13), hCG β subunit (SEQ ID NO: 14, 15) or HIV-1 rev (SEQ ID NO: 40, 41), respectively. Although the antisense sequences claimed each target and modulate expression of their respective gene, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed is structurally and functionally independent and distinct for the following reasons: each antisense sequence has a unique nucleotide sequence, each antisense sequence targets a different and specific region of the target gene, and each antisense, upon binding to the target gene, functionally modulates (increases or decreases) the expression of the gene to a varying degree. Furthermore,

a search of more than one (1) of the antisense sequences claimed in claim 9-22 and 35-38 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for examination. Upon election of any of Groups I, VI, VIII, XIV, XV or XVI, Applicant must further elect one (1) antisense within the elected Group. For example, if Applicant elects Group I, c-myc, Applicant must further elected one of SEQ ID NO: 16-34 for examination on the merits.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-XVIII, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

Art Unit: 1635

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Friday 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
September 9, 2002


PATENT EXAMINER